Docket Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, MD 20852 email: FDADOCKETS@oc.fda.gov

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Docket No. 97N-484S

I am writing to voice my objection to the proposed FDA regulations. Had they been in place at the time I conceive my child, these regulations would have prevented me from choosing the type of semen donor I wanted. I sought an anonymous donor whose identity would be revealed to me while my child was still young because I believe it is the right of every child to know their genetic parentage. Additionally, I sought a donor whom your agency and the Centers for Disease Control classify as "high risk for HIV", gay men. (I have been told that the FDA denies discriminating against "gay men" but wishes to exclude "men who have sex with other men". This rhetorical game makes the FDA appear foolish and I suggest you start being more honest with the public.)

Although my child is still young, he has been already introduced to the donor and when questions come up about his biological parentage, as they inevitably will, I will be able to answer them honestly and openly. Additionally, his donor does play a minor role in his life. I envision the donor's relationship to my child similar to that of an uncle. However large or small that role is, the donor does have a unique role in my child's life and development. I am distressed that the FDA would try to take away this choice. The sperm bank that I used disclosed the donor's sexual orientation to me and, indeed, his sexual practices. None of the other sperm banks I contacted did that. Given the six months quarantine period and the 2-3 month window period for HIV, I felt that this was a reasonable choice for me because I wanted a gay donor. It is wrong for the FDA to define gay men as "high risk" for semen donation given the safeguards already in place. San Francisco Supervisor Mark Leno said when he introduced a resolution against these proposed regulation that these regulations represent "ethnic cleansing of the Lesbian/Gay community". I agree with Supervisor Leno and emphasis that these regulations also limit a woman's right to choose with whom she may conceive. Given the safeguard I have mentioned, these regulations will not increase safety of women such as myself but will only limit our right to choose. Your proposed regulations repeatedly emphasizes that you are trying to increase safety for the recipients. However, in this case, these regulations do not increase safety and would regulate my choice out of existence. I urge you to change this proposal so that this is not the case.

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Sincerely,

Ellen L. Brem

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